Division of Information Technology.

[69 FR 17286, Apr. 2, 2004, as amended at 69 FR 52600, Aug. 27, 2004]

§ 5.1105 Chief Counsel, Food and Drug Administration.

The Office of the Chief Counsel's mailing address is 5600 Fishers Lane, rm. 6–05, Rockville, MD 20857.[1]

§ 5.1110 FDA public information offices.

(a) *Division of Dockets Management (HFA–305).* The Division of Dockets Management public room is located in rm. 1061, 5630 Fishers Lane, Rockville, MD 20852. Telephone: 301–827–6860.

(b) *Division of Freedom of Information (HFI–35).* The Freedom of Information public room is located in rm. 12A–30, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301–827–6567.

(c) *Press Relations Staff (HFI–40).* Press offices are located in rm. 15–A07, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301–827–6242; and at 5100 Paint Branch Pkwy., College Park, MD 20740. Telephone: 301–436–2335.

§ 5.1115 Field structure.

NORTHEAST REGION

Regional Field Office: 158–15 Liberty Ave., Jamaica, NY 11433.

Northeast Regional Laboratory: 158–15 Liberty Ave., Jamaica, NY 11433.

New York District Office: 158–15 Liberty Ave., Jamaica, NY 11433.

New England District Office: One Montvale Ave., Stoneham, MA 02180.

Winchester Engineering and Analytical Center: 109 Holton St., Winchester, MA 01890.

CENTRAL REGION

Regional Field Office: U.S. Customhouse, Second and Chestnut Sts., rm. 900, Philadelphia, PA 19106.

Philadelphia District Office: U.S. Customhouse, Second and Chestnut Sts., rm. 900, Philadelphia, PA 19106.

Baltimore District Office: 6000 Metro Dr., suite 101, Baltimore, MD 21215.

Cincinnati District Office: 6751 Steger Dr., Cincinnati, OH 45237–3097.

Forensic Chemistry Center: 6751 Steger Dr., Cincinnati, OH 45237–3097.

New Jersey District Office: Waterview Corporate Center, 10 Waterview Blvd., 3d floor, Parsippany, NJ 07054.

Chicago District Office: 550 West Jackson Blvd., suite 1500, South Chicago, IL 60661.

Detroit District Office: 300 River Pl., suite 5900, Detroit, MI 48207.

Minneapolis District Office: 212 Third Ave. South, Minneapolis, MN 55401.

SOUTHEAST REGION

Regional Field Office: 60 Eighth St. NE., Atlanta, GA 30309.

Southeast Regional Laboratory: 60 Eighth St. NE., Atlanta, GA 30309.

Atlanta District Office: 60 Eighth St. NE., Atlanta, GA 30309.

New Orleans District Office: 6600 Plaza Dr., suite 400, New Orleans, LA 70122.

Florida District Office: 555 Winderley, suite 200, Maitland, FL 32751.

San Juan District Office: 466 Fernandez Juncos Ave., San Juan, PR 00901–3223.

SOUTHWEST REGION

Regional Field Office: 4040 North Central Expressway, suite 900, Dallas, TX 75204.

Dallas District Office: 4040 North Central Expressway, suite 300, Dallas, TX 75204.

Denver District Office: Bldg. 20, Denver Federal Center, Sixth and Kipling Sts., P.O. Box 25087, Denver, CO 80225–0087.

Kansas City District Office: 11630 West 80th St., Lenexa, KS 66214–3338.

St. Louis Branch: 12 Sunnen Dr., suite 122, St. Louis, MO 63143–3800.

Arkansas Regional Laboratory: 3900 NCTR Rd., Bldg. 26, Jefferson, AR 72079–9502.

[1] The Office of the Chief Counsel (also known as the Food and Drug Division, Office of the General Counsel, Department of Health and Human Services), while administratively within the Office of the Commissioner, is part of the Office of the General Counsel of the Department of Health and Human Services.

Southwest Import District Office: 4040 North Central Expressway, suite 300, Dallas, TX 75204.

PACIFIC REGION

Regional Field Office: 1301 Clay St., suite 1180–N, Oakland, CA 94512–5217.

San Francisco District Office: 1431 Harbor Bay Pkwy., Alameda, CA 94502–7070.

Los Angeles District Office: 19701 Fairchild, Irvine, CA 92612.

Seattle District Office: 22201 23rd Dr. SE., Bothell, WA 98021–4421.

Pacific Regional Laboratory, SW: 19701 Fairchild, Irvine, CA 92612.

Pacific Regional Laboratory, NW: 22201 23rd Dr. SE., Bothell, WA 98021-4421.

PART 7—ENFORCEMENT POLICY

Subpart A—General Provisions

Subpart B [Reserved]

Subpart C—Recalls (Including Product Corrections)—Guidance on Policy, Procedures, and Industry Responsibilities

Subpart D [Reserved]

Subpart E—Criminal Violations

AUTHORITY: 21 U.S.C. 321–393; 42 U.S.C. 241, 262, 263b–263n, 264.

SOURCE: 42 FR 15567, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§ 7.1 Scope.

This part governs the practices and procedures applicable to regulatory enforcement actions initiated by the Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) and other laws that it administers. This part also provides guidance for manufacturers and distributors to follow with respect to their voluntary removal or correction of marketed violative products. This part is promulgated to clarify and explain the regulatory practices and procedures of the Food and Drug Administration, enhance public understanding, improve consumer protection, and assure uniform and consistent application of practices and procedures throughout the agency.

[43 FR 26218, June 16, 1978, as amended at 65 FR 56476, Sept. 19, 2000]

§ 7.3 Definitions.

(a) *Agency* means the Food and Drug Administration.

(b) *Citation* or *cite* means a document and any attachments thereto that provide notice to a person against whom criminal prosecution is contemplated of the opportunity to present views to the agency regarding an alleged violation.

(c) *Respondent* means a person named in a notice who presents views concerning an alleged violation either in person, by designated representative, or in writing.

(d) *Responsible individual* includes those in positions of power or authority to detect, prevent, or correct violations of the Federal Food, Drug, and Cosmetic Act.

(e) [Reserved]

(f) *Product* means an article subject to the jurisdiction of the Food and Drug Administration, including any food, drug, and device intended for human or animal use, any cosmetic and biologic intended for human use, and any item subject to a quarantine regulation under part 1240 of this chapter. *Product* does not include an electronic product that emits radiation and is subject to parts 1003 and 1004 of this chapter.